IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 10/064,749

Confirmation Number: 8455

In re Application of: Robert David Darrow et al.

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Group Art Unit: 3737

Examiner: Joel Lamprecht

Docket Number: RD27658-1

For: MEDICAL DEVICE POSITIONING SYSTEM AND METHOD

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

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June 10, 2009	/Patrick K. Patnode/ Patrick K. Patnode

This Appeal Brief is being filed in furtherance to the Notice of Appeal filed on March 10, 2009.

The Commissioner is authorized to charge the requisite fee of $540.00, and any additional fees that may be necessary to advance prosecution of the present application, to Account No. 07-0868.

Appellants petition to extend the time for Appeal Brief by one month. Please charge the one-month extension of time fee and any other fees required for the subject application to the Assignee's Deposit Account No. 07-0868.

1. REAL PARTY IN INTEREST

The real party in interest is General Electric Company, the Assignee of the above-referenced application by virtue of the Assignment to General Electric Company by Robert David Darrow and Charles Lucian Dumoulin recorded at Reel 012979, Frame 0157, and dated August 13, 2002. Accordingly, General Electric Company, as the parent company of the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. STATUS OF CLAIMS

Claims 1, 2, 4-17 and 19-32 are currently pending, are currently under final rejection and, thus, are the subject of this Appeal. Claims 3 and 18 were canceled. The Examiner rejected claims 13-17, 19-22 and 30-31 under 35 USC § 112, claims 1, 2, 4-10 and 23-29 under 35 USC § 102(b) and claims 11, 12, 24, 25 and 32 under 35 USC § 103(a). Of these, claims 1, 13, 23 and 32 are independent.

4. STATUS OF AMENDMENTS

Appellants have not submitted any amendments subsequent to the Final Office Action mailed on December 11, 2008. Consequently, there are no outstanding amendments to be considered by the Board.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to systems for image guided interventional medical procedures in which a device is inserted into a body during imaging. *See* Application

(published U.S. Patent Application No. 2004/0034297), page 1, paragraph [0002]. More particularly, in certain embodiments, the invention relates to systems that assist in executing the diagnostic and interventional procedures such as assisting in the positioning of the device during the procedures. *See id.*

The Application contains four independent claims, namely, claims 1, 13, 23 and 32, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. Claim 1 relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (*e.g.*, 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a medical device monitoring and positioning subsystem (*e.g.*, 210) for monitoring position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), for providing feedback to an interface unit (*e.g.*, 123), and for repositioning the medical device (*e.g.*, 150) within the target region of interest without moving the subject (*e.g.*, 100) when the position of the medical device (*e.g.*, 150) deviates from the target region of interest. See, *e.g.*, *id.* at page 2, paragraph 0024; see also, FIG. 1; see also, *e.g.*, *id.* at pages 2-3, paragraphs [0026]-[0028]. See, *e.g.*, *id.* at pages 3-4, paragraphs [0030]-[0033].

With regard to the aspect of the invention set forth in independent claim 13, discussions of the recited features of claim 13 can be found at least in the below cited locations of the specification and drawings. Claim 13 also relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (e.g., 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a tracking device (*e.g.*, 151) for tracking a location of the medical device (*e.g.*, 150). The system further includes a processor (*e.g.*, 121) coupled to the imaging device (*e.g.*, 120) and the tracking device (*e.g.*, 151) for generating images of the region of interest with a visual representation of the medical device (*e.g.*, 150) superimposed on the images and the processor (*e.g.*, 121) is further adapted to monitor a position of the medical device (*e.g.*, 150) relative to the region of interest, the processor (*e.g.*, 121) responding to change in the position by repositioning the medical device (*e.g.*, 150) within

the target region of interest without moving the subject (*e.g.*, 100) and providing feedback to an interface (*e.g.*, 123). See, *e.g.*, *id.* at page 2, paragraph 0024; see also, FIG. 1; see also, *e.g.*, *id.* at pages 2-3, paragraphs [0026]-[0028]. See, *e.g.*, *id.* at pages 3-4, paragraphs [0030]-[0033].

With regard to the aspect of the invention set forth in independent claim 23, discussions of the recited features of claim 23 can be found at least in the below cited locations of the specification and drawings. Claim 23 relates to a method for positioning a medical device (*e.g.*, 150). The method includes generating at least one image of a region of interest of a subject (*e.g.*, 100) including a representation of a medical device (*e.g.*, 150) superimposed in the image, monitoring a position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), and providing feedback to an interface (*e.g.*, 123) upon detection of a change in position of the medical device (*e.g.*, 150) relative to the target region and responding to the change by repositioning the medical device (*e.g.*, 150) within the target region of interest without moving the subject (*e.g.*, 100). See, *e.g.*, *id.* at page 2, paragraph [0024]; see also, FIG. 1; see also, *e.g.*, *id.* at pages 2-3, paragraphs [0026]-[0028]. See, *e.g.*, *id.* at pages 3-4, paragraphs [0030]-[0033].

With regard to the aspect of the invention set forth in independent claim 32, discussions of the recited features of claim 32 can be found at least in the below cited locations of the specification and drawings. Claim 32 relates to a medical device positioning system for use during a medical procedure on a subject (*e.g.*, 100) performed during imaging. The system includes a medical device (*e.g.*, 150) adapted for internal use within the subject (*e.g.*, 100) for performing the medical procedure, an imaging device (*e.g.*, 120) for acquiring image data of a region of interest within the subject (*e.g.*, 100), and a medical device monitoring and positioning subsystem (*e.g.*, 210) for monitoring position of the medical device (*e.g.*, 150) relative to a target region of interest within the subject (*e.g.*, 100), for providing feedback to an interface unit (*e.g.*, 123), and for responding to motion of at least one of the medical device (*e.g.*, 150) or the subject (*e.g.*, 100) in a predetermined fashion when the position of the medical device (*e.g.*, 150) deviates from the target region of interest. The predetermined response comprises at least one of terminating therapy, repositioning the medical device within the target region of interest without moving the subject (*e.g.*, 100), activating an audio or text advisory feedback to the interface unit (e.g., 123), or a combination thereof. See, *e.g.*, *id.* at page 2, paragraph [0024]; see also, FIG. 1; see also, *e.g.*, *id.* at pages 2-3, paragraphs [0026]-[0028]. See, *e.g.*, *id.* at pages 3-4, paragraphs [0030]-[0033].

A benefit of the invention, as recited in these claims, is the ability to monitor the movement of a medical device with respect to a target region of interest and control the medical procedure based on the monitoring. For example, as described in the specification, controlling the medical procedure may include terminating the procedure, repositioning the medical device within the target region of interest without moving the subject and/or activating an audio or text advisory feedback to the interface unit. Thus, the disclosed technique improves the efficiency and success rate of the medical procedure. See, *e.g.*, *id*: at pages 3-4, paragraphs [0030]-[0033].

The invention is thus clearly different and distinct from the prior art, as discussed below.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Issue for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 13-17, 19-22 and 30-31 under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

Second Issue for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's second ground of rejection in which the Examiner rejected claims 1, 2, 4-10 and 23-29 under 35 USC 102(b) as being anticipated by Dumoulin et al. (US Patent No. 5,251,635, hereinafter "Dumoulin").

Third Issue for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's third ground of rejection in which the Examiner rejected claim 32 under 35 USC 102(b) as anticipated by Dumoulin, or in the alternative under 35 USC 103(a) as obvious over Dumoulin.

Fourth Issue for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's fourth ground of rejection in which the Examiner rejected claims 24, 25 and 32 under 35USC 103(a) as being obvious over Dumoulin.

Fifth Issue for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's fifth ground of rejection in which the Examiner rejected claims 11 and 12 under 35 USC 103(a) as being unpatentable over Dumoulin and further in view of Panescu et al. (US Patent No. 5,916,163, hereinafter "Panescu").

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Accordingly, Appellants respectfully request full and favorable consideration by the Board, and reversal of the outstanding rejections. Appellants strongly believe that claims 1, 2, 4-17 and 19-

32 are currently in condition for allowance.

A. Ground of Rejection No. 1:

The Examiner rejected claims 13-17, 19-22 and 30-31 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Appellants respectfully traverse this rejection.

The initial burden of proof regarding the sufficiency of the written description falls on the Examiner. Accordingly, the Examiner must present evidence or reasons why persons skilled in the art would not recognize a description of the claimed subject matter in the applicant's disclosure. *In re Wertheim,* 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). The Examiner is also reminded that the written description requirement does not require the claims to recite the same terminology used in the disclosure. The patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), aff'd. 613 F.2d 775 (7th Cir. 1979), cert. denied, 446 U.S. 939 (1980). Moreover, any information contained in any part of the application as filed, including the specification, claims and drawings, may be added to other portions of the application without introducing new matter. Accordingly, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno,* 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985).

Independent Claim 13 and Claims Depending Therefrom.

Independent claim 13 recites, "*A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising: a medical device adapted for internal use within the subject for performing a medical procedure; an imaging device for acquiring image data of a region of interest within the subject; a tracking device for tracking a location of the medical device; and, a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest, the processor responding to change in the position by repositioning the medical device within the target region of interest without moving the subject and providing feedback to an interface.*"

Appellants respectfully submit that the capability of a processor to respond to change in the position of a medical device by repositioning the medical device within a target region of

interest without moving the subject is well understood to a person skilled in the art for a system that could be used for delivery of many different diagnostic and interventional devices. The processor is an integral part of the system; where the system can be used to guide the biopsy needle guide. (*See* Application paragraph 0025).

A portion of the paragraph [0025] reads:

> "Such a system could be used for delivery of many different diagnostic and interventional devices. For example, it could be used to guide the placement of a therapeutic laser, or a biopsy needle guide."

Therefore, claim 13 complies with the written description requirement in the specification. Claims 14-17, 19-22, and 30-31 depend directly or indirectly on claim 13. Accordingly, Appellants respectfully submit that claims 14-17, 19-22, and 30-31 are allowable by virtue of their dependency from allowable base claim. Further, claims 14-17, 19-22, and 30-31 are also allowable by virtue of the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 13-17, 19-22 and 30-31 under 35 USC § 112 be withdrawn.

B. <u>Ground of Rejection No. 2:</u>

The Examiner rejected claims 1, 2, 4-10 and 23-29 under 35 USC 102(b) as being anticipated by Dumoulin. Appellants respectfully traverse this rejection.

For a prior art reference to anticipate under section 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under section 102, a single reference must teach each and every limitation of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Accordingly, the Applicants need only point to a single element not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter. The prior art reference also must show the identical invention "in as complete detail as contained in the ... claim" to support a prima facie case of anticipation. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

The extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir.

1999) (Emphasis Added). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.* In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner, in presenting the inherency argument, bears the evidentiary burden and must adequately satisfy this burden. See id. Regarding functional limitations, the Examiner must evaluate and consider the functional limitation, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *See* M.P.E.P. § 2173.05(g); *In re Swinehart*, 169 U.S.P.Q. 226, 229 (C.C.P.A. 1971); *In re Schreiber*, 44 U.S.P.Q.2d 1429, 1432 (Fed. Cir. 1997). If the Examiner believes the functional limitation to be inherent in the cited reference, then the Examiner "must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art." *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Inter. 1986).

Independent Claims 1 and 23 and Claims Depending Therefrom

Independent claims 1 and 23 recite in generally similar language, *repositioning the medical device within the target region of interest without moving the subject.*

More particularly, independent claim 1 in its current form recites "A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising: a medical device adapted for internal use within the subject for performing the medical procedure; an imaging device for acquiring image data of a region of interest within the subject; and, a medical device monitoring subsystem for monitoring position of the medical device relative to a target region of interest within the subject, for providing feedback to an interface unit, and for repositioning the medical device within the target region of interest without moving the subject when the position of the medical device deviates from the target region of interest."

Independent claim 23, in its current form, recites "A method for positioning a medical device comprising: generating at least one image of a region of interest of a subject including a representation of a medical device superimposed in the image; monitoring a position of the medical device relative to a target region of interest within the subject; and, providing feedback to an interface upon detection of a change in position of the medical device relative to the target region and responding to the change by repositioning the medical device within the target region

of interest without moving the subject."

Appellants have reviewed the Dumoulin reference as a whole and respectfully submit that Dumoulin teaches a tracking device, automatic placement and alignment of the subject by the use of support arm. Dumoulin fails to disclose or suggest positioning of the medical device within the target region of interest without moving the subject. Appellants respectfully submit that the positioning of the medical device within the target region of interest may be achieved in the present application by moving the medical device via a medical device positioning subsystem or a processor. Dumoulin discloses automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device. *See* Dumoulin, column 7, lines 24-27. Clearly, automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device is not same as positioning a medical device within the target region of interest without moving the subject as in the present application. Appellants further submit that tracking and imaging a medical device as in Dumoulin cannot be interpreted as positioning a medical device within the target region of interest.

The Examiner in response to the arguments made by the Appellants, stated that Dumoulin which acquires repeated images of a region of interest including the medical device itself, is sufficient to provide the capability to "monitor and reposition" a device by human hand and eye. (*See* Final Office Action, page 8). Appellants respectfully disagree with the Examiner's position. Dumoulin discloses automatic placement and alignment of the subject by use of a support arm within a desired region around an invasive device. (*See*, column 7, lines 24-27)

Appellants have carefully reviewed Dumoulin and respectfully submit that Dumoulin fails to disclose or suggest a medical device monitoring and positioning subsystem as in the present claims. The monitoring subsystem disclosed in Dumoulin is configured only to track the medical device within the subject by repeated acquisition of images. (*See*, Column 2, lines 59-68 and Column 3, lines 1-6)

The Examiner in his response to the argument that Dumoulin fails to disclose a text of audio advisory as in the present application, stated that Dumoulin provides at least a functional equivalent at least in the form of images. Appellants respectfully disagree with the Examiner's position. Although Dumoulin discloses a superimposed visual icon on the X-ray image of the subject to represent the tracked medical device, Dumoulin fails to disclose providing an audio or text advisory feedback to the interface unit. Clearly, providing an audio or text advisory such as " Device has moved. Laser has been shut down" (*See*, Application paragraph 0032) cannot be

equated with the form of images representing the position of the element itself and in relation to the anatomy as in Dumoulin.

In view of the above arguments, Appellants reiterate that Dumoulin clearly fails to teach each and every element of claims 1 and 23. Hence Dumoulin cannot support a *prima facie* case of anticipation of independent claims 1 and 23.

Claims 2, 4-10 and 24-29 depend directly or indirectly from claims 1 and 23. Accordingly, the Appellants respectfully submit that claims 2, 4-10 and 24-29 are allowable by virtue of their dependency from allowable base claims. Further, claims 2, 4-10 and 24-29 are allowable by virtue of the subject matter they separately recite. Thus, the Appellants respectfully request that the Examiner withdraw the rejection of claims 1, 2, 4-10 and 23-29 under 35 USC 102(b).

C. **Ground of Rejection No. 3:**

The Examiner rejected claim 32 under 35 USC 102(b) as anticipated by Dumoulin or in the alternative under 35 U.S.C. § 103(a) as being unpatentable over Dumoulin. Appellants respectfully traverse this rejection.

The burden of establishing a prima facie case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). In addressing obviousness determinations under 35 U.S.C. § 103, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), reaffirmed many of its precedents relating to obviousness including its holding in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *In Graham*, the Court set out an objective analysis for applying the statutory language of §103:

> Under §103, the scope and content of the prior art are to be determined, differences between the prior art and the claims at issue are to be ascertained, and the level of ordinary skill in the pertinent art are to be resolved. Against this background the obviousness or non-obviousness of the subject matter is to be determined. Such secondary considerations as commercial success, long-felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. *KSR, slip op.* at 2 (citing *Graham*, 383 U.S. at 17-18).

In *KSR*, the Court also reaffirmed that "a patent composed of several elements is not

proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Id. at 14. In this regard, the KSR court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 14-15. Traditionally, to establish a prima facie case of obviousness, the CCPA and the Federal Circuit have required that the prior art not only include all of the claimed elements, but also some teaching, suggestion, or motivation to combine the known elements in the same manner set forth in the claim at issue. See, e.g., *ASC Hospital Systems Inc. v. Montifiore Hospital,* 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984) (holding that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination.); *In re Mills*, 16 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 1990) (holding that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination). In KSR, the court noted that the demonstration of a teaching, suggestion, or motivation to combine provides a "helpful insight" in determining whether claimed subject matter is obvious. KSR, slip op. at 14. However, the court rejected a rigid application of the "TSM" test. *Id.* at 11. In this regard, the court stated:

> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and explicit content of issued patents. The diversity of inventive pursuit and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. *Id.* at 15.

In other words, the *KSR* court rejected a rigid application of the TSM test, which requires that a teaching, suggestion or motivation to combine elements in a particular manner must be explicitly found in the cited prior art. Instead, the KSR court favored a more expansive view of the sources of evidence that may be considered in determining an apparent reason to combine known elements by stating:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the

> marketplace; and the background knowledge possessed by a person having ordinary skill in the art all in order to determine whether there was an apparent reason to combine in the known elements in the fashion claimed in the patent at issue. *Id.* at 14.

The *KSR* court also noted that there is not necessarily an inconsistency between the idea underlying the TSM test and the *Graham* analysis, and it further stated that the broader application of the TSM test found in certain Federal Circuit decisions appears to be consistent with *Graham*. *Id.* at 17-18 (citing *DyStar Textilfarben GmbH and Co. v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (2006) ("Our suggestion test is in actuality quite flexible and not only permits but requires consideration of common knowledge and common sense"); *Alza Corp. v. Mylan Labs, Inc.*, 464 F.3d 1286, 1291 (2006) ("There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires a teaching to combine ... ")).

Furthermore, the *KSR* court did not diminish the requirement for objective evidence of obviousness. Id. at 14 ("To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."); see also, *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002) (holding that the factual inquiry whether to combine references must be thorough and searching, and that it must be based on *objective evidence of record*).

Claim 32

Independent claim 32 recites terminating therapy, repositioning the medical device within the target region of interest without moving the subject, activating an audio or text advisory feedback to the interface unit, or a combination thereof. "The advisory feedback includes an output notification to operator, such as through interface 123 of FIG. 1 that movement of the medical device relative to the target region of interest has occurred. For example, advisory feedback may include audio output such as "Device has moved. Laser has been shut down";

text output such as "Device has moved. Do you wish to reposition?"; and, visual output. (See Application, paragraph 0032)

The Examiner failed to apply a reference that includes all of the recited features of claim 32. Appellants respectfully submit that Dumoulin does not describe any claimed predetermined or pre-programmed responses such as terminating therapy or repositioning the medical device within the target region of interest without moving the subject or activating an audio or a text advisory feedback to the interface unit whatsoever. Thus, Dumoulin does not teach or suggest all of the recitations of the claim 32.

MPEP 2143.03 states that,

[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

Appellants respectfully submit that, as stated above, there is no teaching or suggestion of any claimed predetermined or pre-programmed responses in Dumoulin. In view of the foregoing considerations, Appellants contend that the reference fails to establish a *prima facie* case of anticipation or obviousness of claim 32. Claim 32 is therefore believed to be clearly patentable over the cited reference. Its consideration and allowance is respectfully requested.

D. Ground of Rejection No. 4:

The Examiner rejected claims 24, 25 and 32 under 35USC 103(a) as being obvious over Dumoulin. Appellants respectfully traverse this rejection.

With regard to claims 24, 25 and 32, claims 24, 25 and 32 recite in generally similar language *activating an audio or text advisory feedback to the interface unit.* (*See* Application paragraph 0032, 0033) Dumoulin fails to disclose the claimed predetermined or pre-programmed response such as terminating therapy or activating an audio or a text advisory feedback to the interface unit. Appellants reiterate that while Dumoulin discloses superimposed visual icon on the X-ray image of the subject to represent the tracked medical device, Dumoulin fails to teach or suggest an audio or text advisory feedback such as "Device has moved. Laser has been shut down" or text output such as "Device has moved. Do you wish to reposition?" (See Application, paragraph 0027 and 0032). Clearly, the visual icon representing the tracked medical device in Dumoulin cannot be equated to displaying text or audio advisory feedback as

in the present application. Therefore, no *prima facie* case of obviousness exists for claims 24, 25 and 32.

E. Ground of Rejection No. 5:

The Examiner rejected claims 11 and 12 under 35 USC 103(a) as being unpatentable over Dumoulin and further in view of Panescu. Appellants respectfully traverse this rejection.

As stated above, Dumoulin does not teach, suggest or disclose each and every aspect of Appellants' invention as claimed in independent claim 1. Claims 11 and 12 depend directly or indirectly from claim 1 and are allowable by virtue of their dependency from the base claim. Further, the claims are allowable for the subject matter they separately recite. Thus, it is respectfully requested that the rejections of claims 11 and 12 under 35 USC 103(a) be withdrawn.

Conclusion

For the reasons set out above, Appellants respectfully submit that the application is in condition for allowance. Favorable reconsideration and allowance of the application are, therefore, respectfully requested.

If the Examiner or Board believes that anything further is necessary to place the application in better condition for allowance, the Examiner or Board is kindly asked to contact Appellants' undersigned representative at the telephone number below.

Respectfully submitted,

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8. APPENDIX OF CLAIMS ON APPEAL

Listing of Claims:

1. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing the medical procedure;

an imaging device for acquiring image data of a region of interest within the subject; and,

a medical device monitoring subsystem for monitoring position of the medical device relative to a target region of interest within the subject, for providing feedback to an interface unit, and for repositioning the medical device within the target region of interest without moving the subject when the position of the medical device deviates from the target region of interest.

2. The system of claim 1 wherein the medical device monitoring and positioning subsystem is adapted to receive configuration information corresponding to the medical device and wherein the configuration information comprises at least one of three-dimensional (3D) coordinates of the device, tracking method information corresponding to the medical device, physical dimensions of the device and a model representation of the device.

4. The system of claim 1 wherein the medical device monitoring and positioning subsystem is further adapted for responding to motion of at least one of the medical device or the subject in a predetermined fashion, wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image, activating an advisory message to the interface unit, or a combination thereof.

5. The system of claim 1 wherein the medical device monitoring and positioning subsystem is further adapted for providing advisory feedback to the interface unit.

6. The system of claim 5 wherein the advisory feedback comprises at least one of a visual icon representing position of the device, a text message and an audio advisory.

7. The system of claim 1 further comprising a tracking device for tracking a location of the medical device.

8. The system of claim 1 wherein the imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

9. The system of claim 1 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

10. The system of claim 1 wherein the interface is further adapted to respond to operator input of coordinates marking a desired target position for the medical device.

11. The system of claim 2 wherein the medical device configuration information comprises information corresponding to a plurality of medical device types and includes a visual representation of the medical device for superimposing on the images based on the device configuration information for a selected medical device.

12. The system of claim 11 wherein the visual representation of the medical device is a wire-frame model of the medical device.

13. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing a medical procedure;

an imaging device for acquiring image data of a region of interest within the subject;

a tracking device for tracking a location of the medical device; and,

a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest, the processor responding to change in the position by repositioning the medical device within the target region of interest without moving the subject and providing feedback to an interface.

14. The system of claim 13 wherein the medical imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

15. The system of claim 13 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

16. The system of claim 13 wherein the interface is coupled to the processor for displaying the images representing the region of interest and the visual representation of the medical device, the interface being for use in positioning the medical device during the medical procedure and being further adapted to respond to movement of the medical device in real-time.

17. The system of claim 13 wherein the feedback provided comprises at least one of a visual icon representing position of the device, a text message, and an audio advisory.

19. The system of claim 13 wherein the processor is further adapted to provide an advisory response when the medical device deviates from a specified target position.

20. The system of claim 13 wherein the processor further includes medical device configuration information corresponding to a plurality of medical device types and wherein the visual representation of the medical device on the images is based on the device configuration information for a selected medical device.

21. The system of claim 20 wherein the visual representation of the medical device is a wire-frame model of the medical device.

22. The system of claim 13 wherein the processor is further adapted to respond in a predetermined fashion if the medical device position deviates by a specified distance from the target region of interest and wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image, activating an advisory message to the interface unit or a combination thereof.

23. A method for positioning a medical device comprising:

generating at least one image of a region of interest of a subject including a representation of a medical device superimposed in the image;

monitoring a position of the medical device relative to a target region of interest within the subject; and,

providing feedback to an interface upon detection of a change in position of the medical device relative to the target region and responding to the change by repositioning the medical

device within the target region of interest without moving the subject.

24. The method of claim 23 wherein the feedback comprises at least one of a first visual icon representing position of the device and a second visual icon representing the target region of interest, a text message, an audio advisory and a response to the change in a predetermined fashion.

25. The method of claim 24 wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image, activating an advisory message to the interface unit, or a combination thereof.

26. The method of claim 23 wherein the interface is adapted to respond to operator input of coordinates marking a target position of the medical device.

27. The method of claim 23 wherein image data is acquired using of at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

28. The method of claim 23 further comprising the step of navigating the medical device to a target region of interest based on the feedback.

29. The system of claim 1 further comprising the step of navigating the medical device during the medical procedure based on the feedback.

30. The system of claim 13 further comprising the step of navigating the medical device during the medical procedure based on the feedback.

31. The system of claim 13 wherein the interface is further adapted to respond to operator input of coordinates marking a target position of the medical device.

32. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing the medical procedure;

an imaging device for acquiring image data of a region of interest within the subject; and

a medical device monitoring and positioning subsystem for monitoring position of the

medical device relative to a target region of interest within the subject, for providing feedback to an interface unit, and for responding to motion of at least one of the medical device or the subject in a predetermined fashion when the position of the medical device deviates from the target region of interest, wherein the predetermined response comprises at least one of terminating therapy, repositioning the medical device within the target region of interest without moving the subject, activating an audio or text advisory feedback to the interface unit, or a combination thereof.

9. APPENDIX OF EVIDENCE

None.

10. APPENDIX OF RELATED PROCEEDINGS

None.